Heraeus

K101617

Technical File

Summary of safety and effectiveness of the Impression material Flexitime Xtreme 2

1. Submitter name

Heraeus Kulzer, LLC
300 Heraeus Way
South Bend, Indiana 46614

SEP 0 7 2010

Contact person: Cheryl V. Zimmerman
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Date summary prepared: April, 21, 2010

2. Name of the device:

Flexitime Xtreme 2 Light Flow/Medium Flow/Heavy Tray
The product is Regulatory Class II and the product code ELW
It is used as dental impression material.

The GMDN number is 35866 and the description is Impression material, dental, silicon rubber , the UMDS number is 16-679 and the description is Dental-Abdruckmaterial, Silikongummi.

3. Substantially equivalence

Flexitime Xtreme 2 (Project Name D 948) is a revised version of the product Flexitime Xtreme (K042878). The main components and their ratio in Flexitime Xtreme and Flexitime Xtreme 2 are similar. Flexitime Xtreme 2 contains as an additional raw material Heptamethyltrisloxane, Polyalkyleneoxid modified(CAS 27306-78-1) (K091494), which has been already used in Flexitime Light Flow and Medium Flow.

4. Description of the device

The products are developed under the project name D 948. The Flexitime Xtreme 2 Light Flow , Medium Flow and Heavy Tray each are addition-cross-linking polyvinyl siloxane impression materials , all delivered in 50 ml cartridges, and are part of the Flexitime Xtreme -system. The Flexitime Xtreme

2 assortment is characterised by the addition of Blackbeery-aroma and is technically characterized by a short working time of appr. 1.5 min and a short time in mouth period of min. 1.5 min.. These products, which show a shorter working time and setting time, are highly desired for single step impressions especially in combination with the double arch impression technique.
The materials were developed to ensure hydrophilic characteristics for optimal impression taking in the wet surroundings of the mouth combined with good mechanical properties. The materials are based on the existing materials D 919 (Flexitime Light Flow and Flexitime Medium Flow) and Flexitime Xtreme Heavy Tray to meet the requirements of the US market. Flexitime Light Flow and Flexitime Medium Flow are marketed since August 2009 and Flexitime Xtreme Heavy Tray is marketed since March 2006.

For the types D 948 Light Flow, D 948 Medium Flow and D 948 Heavy Tray the following accepted laboratory prototypes have been compiled: PDE 704-2/PDE 705-2, PDE 694-1/PDE 695-2 und PDE 702-1/PDE 703-1.

The target-performance comparisons prove that the requirements of the functional specification are fulfilled by these laboratory products. The prototypes were provided for further development and the upscaling by the process development department shows the functional specifications are fulfilled also for the scale up material.

The products fulfill all requirements of the EN ISO 4823: 2007.

5. Intended use

Flexitime Xtreme 2 is an addition-cross-linking polyvinyl siloxane impression material for all inlay, crown and bridge, edentulous and partial impressions.

6. Summaries

a: See point 3

b: (1) Nonclinical- tests: In accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with EN ISO 10993-1.

The biological compatibility of Flexitime Xtreme 2 was verified in accordance with the international standards.

The biocompatibility of Flexitime Xtreme 2 in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit/risk-relation has been judged as positive.

(2) Clinical Evaluation

In accordance with the medical Device directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes a clinical evaluation in accordance with MEDDEV 2.7.1., which is intended to critically evaluate the clinical benefits of the medical device in comparison to its potential risks. Therefore, any clinical evaluation is part of the compulsory risk management process according to EN ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device.

On this background, the clinical evaluation was performed in order to comply with the current European medical device legislation, in particular with MEDDEV 2.7.1. This critical evaluation followed the procedures outlined in the corresponding clinical evaluation plan.

Flexitime Xtreme 2 is an impression material system, which is generally classified as a class I medical device under the Medical Device Directive 93/42/EEC.
Considering the evaluated scientific data and technical results for Flexitime Xtreme 2 it is concluded that the products can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against their benefits in dentistry. Therefore, a positive benefit versus risk ratio can be stated by the experts for Flexitime Xtreme 2, provided that the products applied in accordance with its intended use as outlined in the manufacturer's instruction for use.

The clinical evaluation report was prepared in accordance with MEDDEV 2.7.1 and followed the provisions of the corresponding clinical evaluation plan.

(3) Conclusion

A positive benefit versus risk ratio can be stated by the experts for Flexitime Xtreme 2, provided that the product applied in accordance with its intended use as outlined in the manufacturer's instruction for use for the clinical and the non-clinical test results.

(c) 510 (k) summary

The risk potential of the Flexitime Xtreme 2 was proved considering the current composition. All properties of the product were verified successfully.

The biological compatibility of the impression material was investigated to evaluate the toxicological risk. A toxicological evaluation report has confirmed that the product Flexitime Xtreme 2 meets the requirements of the DIN EN ISO 10993 standard. The results were discussed in a Biocompatibility Evaluation Report and the benefit/risk-relation has been judged as positive.

The physical properties of Flexitime Xtreme 2 were determined in accordance with EN ISO 4823. The results have shown good properties of Flexitime Xtreme 2 in accordance to this standard.

Based on the results of the clinical evaluation report it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighted against their benefits in dentistry.

The risk analysis (according to DIN EN ISO 14971) was carried out for Flexitime Xtreme 2 and showed that the application of Flexitime Xtreme 2 could be considered to be safe.

Flexitime Xtreme meets all requirements relevant for dental impression material in accordance with the Medical Device directive 93/42/EWG and national European medical device legislation. Based on the actual facts Flexitime Xtreme 2 could be evaluated to be effective and safe with its intended use as outlined in the manufacturer's instruction for use.

Dormagen, 01.09.2010

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Cheryl Zimmerman
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Heraeus Kulzer, LLC
300 Heraeus Way
South Bend, Indiana 46614

SEP 07 2010

Re: K101617
Trade/Device Name: Flexitime Xtreme 2
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: June 2, 2010
Received: June 9, 2010

Dear Ms. Zimmerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K101617

Device Name: *Flexitime Xtreme 2*

SEP 07 2010

Indications For Use:

Flexitime Xtreme 2 is an addition-cross-linking polyvinyl siloxane impression material for all inlay, crown and bridge, edentulous and partial impressions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use ✓ OR

(Per 21 CFR 801.109)

Over-The-Counter Use _____

(Division Sign-Off) (Optional Format 1-2-96)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101617